STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HOS00126	A. BUILDING _____ B. WING _____	C 11/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN AND INFANTS HOSPITAL OF RHODE ISLANI	101 DUDLEY STREET PROVIDENCE, RI 02905

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 160	ORGANIZATION & MANAGEMENT 12.2 Organization 12.2 Each hospital department and service shall maintain: a) clearly written definitions of its organization, authority, responsibility and relationships; b) written patient care policies and procedures; and c) written provision for systematic evaluation of programs and services. This Requirement is not met as evidenced by: Based on a review of medical records, staff interviews, and review of hospital policies, it was determined that the hospital failed to ensure compliance with the following hospital policies: 1. "Surgical Counts", for relevant sample patient ID #2; 2. "Tamponade Ballon Catheter" and "Report (Hand Off Communication)" for relevant sample patient ID # 3; and, 3. "Informed Consent", for 5 of 8 relevant sample patients (ID #'s 10, 11, 12, 13 and 15). Findings are as follows: 1. A review of the hospital policy entitled, "Surgical Counts", Section G. "Inaccurate Counts", states: Under item #2, "Obtain order for X-ray". Under item #3, "Document physician review of X-ray in the medical record". A review of the medical record for patient ID #2 revealed a "Robot assisted hysterectomy, bilateral salpingo-oophorectomy, bilateral pelvic and periaortic lymph node dissection" on 8/25/10. An Occurrence Report submitted by the	Z 160		

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Z 160	Continued From page 1 Circulating Nurse dated 8/25/10 revealed that during the procedure, the Scrub Technician noted that a "sponge had separated", resulting in a missing blue radiopaque string. The Surgeon was notified, and with visual inspection determined that this radiopaque string had been retained in the patient's abdomen, and "was able to find and remove it". The patient was seen on 9/13/10 for an irritation of the wound site. When this persisted and there was a concern for cellulitis, a CT scan of the abdomen was performed on 9/27/10 and revealed a 4.8 X 1 cm (centimeter) fluid collection of the anterior wall superficial to the peritoneum, with a foreign body noted extending through the wall and into the peritoneal space. The patient returned to the Operating Room on 10/5/10 for a wound exploration. A Pathology Report dated 10/6/10 revealed "multiple fragments of light blue-red pieces ranging in measurement from 1.7 x 12.5 cm". During an interview with the Scrub Technician on 10/28/10 at 12:10 PM, it was reported that when the radiopaque string had been retrieved by the Surgeon with the initial surgery on 8/25/10, it had been measured against another similiar sponge string and "appeared to be the same in size." The surgical team "felt confident that all the radiopaque string had been removed", therefore an X-ray was not requested to confirm that the string had been retrieved in its entirety. During an interview on 10/28/10 at 10:20 AM with the Surgeon, it was reported that the sponge had been delivered through the trocar during the surgery to "blot any bleeding" in order to provide visualization of the site. When the Surgeon was made aware by the Scrub Technician that a blue	Z 160		

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Z 160	Continued From page 2 radiopaque string from a sponge utilized during the procedure was missing, a laparoscope was utilized and "this long blue string was visualized". It was removed, and the Surgeon then proceeded to do another "sweep" visualization to be sure all the string had been removed. The Surgeon stated, that at that point, "I had no doubt that I had gotten it all." With the string retrieved, it was determined that "an X-ray was not needed." During an interview on 10/25/10 at 10:00 AM with the Risk Manager, it was reported that there has been no other occurrences regarding missing sponge strings. The hospital immediately changed the sponges used in the pelviscopy trays, and notified the manufacturer. They also put an action plan in place that included "if there is any question in regards to a product (sponge/equipment) used during a surgical procedure, an X-ray will be obtained prior to closure to confirm no retained foreign object", and "sponges will be unfolded and inspected prior to procedure". Although the sponge count was correct, the hospital failed to ensure that all fragments from the radiopaque string had been accounted for by obtaining an X-ray. 2. A review of the hospital policy entitled "Tamponade Balloon Catheter", under "Purpose", states: "In the event of a postpartum hemorrhage, the OB (Obstetrical) physician may insert a tamponade balloon catheter into the uterus in an effort to achieve hemostasis." Under "Procedure: Assisting with Vaginal Placement of the Tamponade Balloon Catheter",	Z 160		

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Z 160	Continued From page 3 it states: Under item # 11, "The vaginal canal may be packed with vaginal sponges if desired by provider.....Count the sponges prior to insertion and document in electronic record." Under "Assisting with Removal of Tamponade Balloon Catheter", it states: Under item #1, "Removal of the balloon catheter is performed by the physician within 24 hours of placement", and under bullet #2 it states: "Remove and count vaginal sponges if placed (obtain X-ray if sponge count is not correct)." A review of the hospital policy entitled, "Report (Hand Off Communication)", under "Purpose", it states: "To assure that adequate information is communicated to caregivers." Under "Policy", item #1 states: "A caregiver to caregiver report (hand off communication) is given when a patient's care is transferred from one caregiver to another...." Under item #3, it states: "The report includes but is not limited to....Assessment..... equipment." A review of the medical record for patient ID # 3 revealed a spontaneous vaginal delivery resulting in a viable female infant on 7/24/10. The patient was noted with postpartum bleeding despite administration of Pitocin, Misoprostol, and Hemabate. A decision was made to place a Bakri (tamponade) balloon to control bleeding. Surgical documentation revealed that this was	Z 160		

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Z 160	Continued From page 4 done under ultrasound guidance and "A Bakri balloon was guided until the tip reached the fundus of the uterus, and then it was held in place as a second provider inflated the balloon with fluid up to 300 ml (milliliters). After this, one roll of Kerlix was placed into the vagina to hold the Bakri Balloon in place." Further documentation by nursing revealed that the balloon was slowly deflated by a two residents. At 10:00 PM on 7/25/10, a nurse's note revealed, "Bakri balloon out." During an interview on 10/25/10 at 9:50 AM with the Risk Manager, it was reported that this patient presented to the clinic on 9/28/10 for complaints of a foul vaginal odor. During physician examination, the Kerlix roll was discovered and removed from the vaginal cavity. The patient was placed on prophylactic antibiotics. During an interview with the Chief Resident on 10/26/10 at 12:35 PM, it was reported that after the Bakri Ballon had been placed, the Obstetrical team changed. During the team "handoff", which occurs twice a day, the teams meet to discuss the status of all patients being followed. In this case, it had not been communicated that there was a Kerlix sponge in place with the Bakri balloon. This resulted in the sponge not being removed and accounted for when the balloon fell out. The Chief Resident also reported that not all providers utilize sponges with the Bakri balloon procedure. The Kerlix sponge use is dependent on cervical dilation, and when needed, is used to prevent the balloon from falling out. It was reported that it is not unusual for the sponge to fall out when the balloon comes out. During an interview on 10/27/10 at 10:30 AM with the Chief of Obstetrics, it was reported that this	Z 160		

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Z 160	Continued From page 5 balloon has been utilized for approximately 2 years at the hospital, with no previous occurrences. The hospital utilizes this balloon approximately 25 times per year. The Medical Staff and Residents did attend a simulation in November of 2009, which included the management of postpartum hemorrhage and blood loss estimates at delivery, and the use of the Bakri ballon with a Power Point presentation. During the interview with the Risk Manager, it was reported that the hospital has an action plan in place to standardize a documentation form for placement, care and removal of the Bakri ballon, including clear documentation of use of sponges. In addition, standardization of communication handoff between residents is also planned. It was determined that the hospital failed to ensure compliance with the Bakri ballon procedure relevant to the counting of vaginal sponges when this balloon is removed. The hospital also failed to follow their hospital policy and standard of practice relevant to adequate communication of information between caregivers. 3. A review of the hospital policy entitled "Informed Consent" states, under "Policy": "The exact date and time at which consent was obtained must be indicated". 1. A review of the medical record for patient ID #10 revealed a surgical procedure on 10/18/10. 2. A review of the medical record for patient ID #11 revealed a surgical procedure on 10/8/10.	Z 160		

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Z 160	Continued From page 6 3. A review of the medical record for patient ID #12 revealed a surgical procedure on 10/19/10. 4. A review of the medical record for patient ID #13 revealed a surgical procedure on 10/8/10. 5. A review of the medical record for patient ID #15 revealed a surgical procedure on 8/2/10. A review of the "Operative Consents" for all above patients revealed no documented times that these consents were obtained, per the hospital policy. During an interview on 10/29/10 at approximately 1:30 PM, with both the Nurse Manager of Surgical Services and the Risk Manager, neither could provide evidence that the times the consents were obtained had been documented in the Informed Consents, in accordance with the hospital policy.	Z 160		
Z 370	PATIENT CARE SERVICES 19.6 Patient Care Management 19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by: Based on record review and staff interviews, it was determined that the hospital failed to provide care and services in accordance with the prevailing community standard of care. Findings are as follows: Refer to Z 160.	Z 370		